

RESULTS OF INVESTIGATION: Analysis showed that the *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* contained approximately (12,056-vial lot) 81 percent, (portion of 10-ctn. lot) 51 percent, and (19,640-vial lot) 82 percent of the declared amount of penicillin. The 7,854-vial lot of *procaine penicillin G in aqueous suspension* and the 19,640-vial lot and 3,086-vial lot of *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* bore labels containing expiration dates which had expired.

LIBELED: 2-8-62, E. Dist. Pa.

CHARGE: *Procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* (12,056-vial lot, 19,640-vial lot, and portion of 10-ctn. lot), 501(c)—when shipped and while held for sale, the strength of the article differed from that which it was represented to possess, namely, "Each 2 cc dose contains 400,000 units of crystalline procaine penicillin G."

502(1)—when shipped and while held for sale, the *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* (all lots) was composed in part of a kind of penicillin and of a streptomycin derivative, and the *procaine penicillin G in aqueous suspension* (all lots) was composed in part of a kind of penicillin, and such articles were not from batches with respect to which certificates or releases were in effect pursuant to 507 and the articles were not exempt from that requirement.

DISPOSITION: 4-18-62. Default—destruction.

6908. Various prescription drugs. (F.D.C. No. 46960. S. Nos. 54-861/72 T.)

QUANTITY: 2,671 tablets and capsules and 69½ pts. of liquid drugs at Jacksonville, Fla., in possession of Hermax Corp.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Florida and (some labels), the names and addresses of manufacturers, packers, or distributors outside the State of Florida.

LIBELED: 2-5-62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the statement "Professional Sample" or similar wording on the labels of a number of the articles was false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(2)—a number of the articles failed to bear labels containing the common or usual name of each active ingredient; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations; 502(1)—a number of the articles were drugs composed in whole or in part of a kind of penicillin, and were not from batches with respect to which certificates or releases were effective pursuant to 507 in that certification of the articles under their present labels had not been obtained; and 503(b)(4)—a number of the articles were subject to the provisions of 503(b)

(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 3-7-62. Default—destruction.

DRUGS FOR VETERINARY USE

6909. Medicated feed. (F.D.C. No. 46853. S. No. 34-811 T.)

QUANTITY: 87 50-lb. bags at Colfax, N. Dak., in possession of Colfax Grain Co.

SHIPPED: 10-27-61, from Willmar, Minn.

LABEL IN PART: "Richland Quality 18% Pig Starter Medicated \* \* \* Active Drug Ingredient Arsanilic Acid 0.0016%; Manganese Bacitracin 60 Grams Per Ton; Procaine Penicillin 20 Grams Per Ton Net Weight 50 Lbs. Manufactured by Colfax Grain Company, Colfax, North Dakota."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer from arsanilic acid shipped in interstate commerce as described above. Analysis showed that the article contained 6 times the labeled amount of arsanilic acid.

LIBELED: 12-14-61, Dist. N. Dak.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Arsanilic Acid 0.0016%" was false and misleading as applied to the article which contained an excess of that ingredient; 502(1)—the article was a drug composed in part of manganese bacitracin and procaine penicillin, and it was not from a batch with respect to which a certificate or release was in effect pursuant to 507 and it was not exempt from such certification since it contained less than the required amount of the active drug ingredient for the treatment of bacterial enteritis in swine for which it was intended, and in that the label failed to bear adequate directions and warnings for use by reason of failure on its label to bear the warning concerning the five day withdrawal prior to slaughter for human consumption, which warning was required by regulations for animal feeds containing an arsenical.

DISPOSITION: 3-2-62. Default—destruction.

6910. Medicated feed. (F.D.C. No. 46456. S. No. 6-008 T.)

QUANTITY: 30 100-lb. bags at Methuen, Mass.

SHIPPED: 7-14-61, from Deposit, N.Y., by Delaware Milling Co., Inc.

LABEL IN PART: "Pellets \* \* \* Delaware Broiler Finisher Medicated \* \* \* Active Drug Ingredients Dienestrol Diacetate 0.0035% Nicarbazin 0.0125% Arsanilic Acid 0.0090% \* \* \* Feed Ingredients \* \* \* Zinc Bacitracin \* \* \* Manufactured by Delaware Milling Company, Inc. Deposit, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article contained only a trace of arsanilic acid.

LIBELED: 9-14-61, Dist. Mass.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Arsanilic Acid 0.0090%" was false and misleading when applied to the article which contained less than the declared amount of arsanilic acid; and 502(1)—the article contained dienestrol diacetate, nicarbazin, arsanilic acid, and zinc bacitracin, and they were not from batches with respect to which a certificate or release had been issued pursuant to 507.